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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,507	02/05/2004	Taejoon Kwon	YPL-0080	6812
23413	7590	09/28/2006	EXAMINER	
CANTOR COLBURN, LLP 55 GRIFFIN ROAD SOUTH BLOOMFIELD, CT 06002			ZHOU, SHUBO	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/773,507

Applicant(s)

KWON, TAEJOON

Examiner

Shubo (Joe) Zhou

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/7/04</u> , <u>4/4/05</u> | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-12 are currently pending and under examination.

Sequence Rules Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). Such sequence is present in Figure 6. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because a paper copy, a computer readable form of a Sequence Listing containing this sequence, and a statement under 37 CFR 1.821(f) are not provided.

Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action including providing a paper copy, a computer readable form of a Sequence Listing containing this sequence, and a statement under 37 CFR 1.821(f). Applicants are reminded that it is required that SEQ ID Nos be amended into the specification at each sequence, and that when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings. Failure to comply with these requirements may result in ABANDONMENT of the application under 37 CFR 1.821(g).

Information Disclosure Statement

The Information Disclosure Statements filed 5/7/04 and 4/4/05 are acknowledged. The documents listed in the PTO-1449 filed 5/7/04 have been considered. The documents listed

on the PTO-1449 filed 4/4/05 have been struck-through on the form because all the documents listed therein are duplicates of the documents listed on the PTO-1449 filed 5/7/04.

Specification

The specification is objected to because of the following informalities:

The phrase “2nd” on page 1, line 30, is confusing. Is “and” intended?

The phrase “... enables to construction of ...” on page 1, lines 31-32 is confusing.

It seems that the word “interest” on page 3, line 22, should be “interested.”

Appropriate correction is required.

Claim Rejections-35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a method process or a system for performing the process or a computer readable medium comprising computer program embodies thereon for the method, for designing probes using heterogeneous genetic information. The process comprises creating a crosslink map having records about genome sequences, searching the information, determining a reference group, calculating difference values, and determining location of target genetic information.

The following analysis of facts of this particular patent application follows the rationale suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject

Matter Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at <http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm>).

The Guidelines states:

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):

- *The claimed invention "transforms" an article or physical object to a different state or thing.*
- *The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.*

In the instant case, at least one embodiment of the claimed invention merely manipulates data or information, calculates numbers, and results in determining locations of target genetic information. The process does not transform an article or physical object to a different state or thing outside a computation device.

Furthermore, the invention does not produce a useful, concrete and tangible result. Specifically it does not produce a tangible result. The preamble indicates the process is for designing probes using heterogeneous genetic information. However, the process steps end in determining the locations of target genetic information without using or making available for use the result of the manipulation to enable its functionality and usefulness to be realized. S

Additionally, while claim 12 is drawn to a computer readable medium comprising computer program embodied thereon, since "computer readable medium" is defined in the specification page12, line 32, as including "carrier waves," which is a signal, at least one embodiment of the claimed invention is drawn to a signal.

Claims that recite nothing but the physical characteristics of a form of energy, such as a frequency, voltage, or the strength of a magnetic field, define energy or magnetism, per se, and as such are nonstatutory natural phenomena. O'Reilly, 56 U.S. (15 How.) at 112-14. Moreover, it

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does not appear that a claim reciting a signal encoded with functional descriptive material falls within any of the categories of patentable subject matter set forth in § 101 for the following reasons as set forth in the “Guidelines:”

First, a claimed signal is clearly not a “process” under § 101 because it is not a series of steps. The other three § 101 classes of machine, compositions of matter and manufactures “relate to structural entities and can be grouped as ‘product’ claims in order to contrast them with process claims.” 1 D. Chisum, Patents §1.02 (1994). The three product classes have traditionally required physical structure or material.

“The term machine includes every mechanical device or combination of mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result.” Corning v. Burden, 56 U.S. (15 How.) 252, 267 (1854). A modern definition of machine would no doubt include electronic devices which perform functions. Indeed, devices such as flip-flops and computers are referred to in computer science as sequential machines. A claimed signal has no physical structure, does not itself perform any useful, concrete and tangible result and, thus, does not fit within the definition of a machine.

A “composition of matter” “covers all compositions of two or more substances and includes all composite articles, whether they be results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.” Shell Development Co. v. Watson, 149 F. Supp. 279, 280, 113 USPQ 265, 266 (D.D.C. 1957), aff’d, 252 F.2d 861, 116 USPQ 428 (D.C. Cir. 1958). A claimed signal is not matter, but a form of energy, and therefore is not a composition of matter.

The Supreme Court has read the term “manufacture” in accordance with its dictionary definition to mean ‘the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.’ Diamond v. Chakrabarty, 447 U.S. 303, 308, 206 USPQ 193, 196-97 (1980) (quoting American Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11, 8 USPQ 131, 133 (1931), which, in turn, quotes the Century Dictionary). Other courts have applied similar definitions. See American Disappearing Bed Co. v. Arnaelsteen, 182 F. 324, 325 (9th Cir. 1910), cert. denied, 220 U.S. 622 (1911). These definitions require physical substance, which a claimed signal does not have. Congress can be presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change. Lorillard v. Pons, 434 U.S. 575, 580 (1978). Thus, Congress must be presumed to have been aware of the interpretation of manufacture in American Fruit Growers when it passed the 1952 Patent Act.

A manufacture is also defined as the residual class of product. 1 Chisum, § 1.02[3] (citing W. Robinson, The Law of Patents for Useful Inventions 270 (1890)). A product is a tangible physical article or object, some form of matter, which a signal is not. That the other two product classes, machine and composition of matter, require physical matter is evidence that a manufacture was also intended to require physical matter. A signal, a form of energy,

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does not fall within either of the two definitions of manufacture. Thus, a signal does not fall within one of the four statutory classes of § 101.

On the other hand, from a technological standpoint, a signal encoded with functional descriptive material is similar to a computer-readable memory encoded with functional descriptive material, in that they both create a functional interrelationship with a computer. In other words, a computer is able to execute the encoded functions, regardless of whether the format is a disk or a signal.

These interim guidelines propose that such signal claims are ineligible for patent protection because they do not fall within any of the four statutory classes of § 101. Public comment is sought for further evaluation of this question.

Thus, claim 12 is drawn to nonstatutory subject matter.

Claim Rejections-35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims appear to be drawn to a method or system or computer program for “designing a probes [sic] using heterogeneous genetic information.” The method steps, however, end with “determining the location of the target genetic information” (see claim 7), and never accomplish such “designing” probes. It is thus not clear whether such designing action is required in the claim and what other steps are required to achieve the designing.

The phrase “the version of the genome sequence” recited in lines 3-4 of claim 1, in lines 3-4 of claim 7, and in lines 4-5 of claim 12, lacks clear antecedent basis and is confusing. It is not clear whether the “version” means the published version of a genome sequence from a particular institution. It is also not clear whether the term “a genome sequence” is the entire

DNA sequence of a genome of a particular organism or is any genomic sequence obtained from a genome.

The phrase “the genome sequence in the crosslink map” recited in line 7 of claim 1 lacks clear antecedent basis. It is not priorly recited that a genome sequence in a crosslink map, but only “records according to the version of a genome sequence,” is in the map.

The metes and bounds of the limitation “difference values of the start positions and the end positions of the of the reference genetic information based on the crosslink map” recited in claim 1, lines 10-11, etc. are not clear. It is not clear between what is the difference value: difference values between the start positions of the target genetic information and the reference genetic information, difference values between the end positions of the target genetic information and the reference genetic information, difference values between the start position and the end position of the of the target genetic information or of the reference genetic information, or else. Ditto for the same phrase recited in independent claims 7 and 12.

The metes and bounds of “the latest genome sequence” recited in line 12 of claim 1, and in line 5 of claim 5, etc. are not clear. It is not clear what is meant by “latest genome sequence.” It is unclear whether it is meant the latest version of a genome sequence of a particular organism sequenced or published by a particular institution or person, and it is unclear “latest” by what time, e.g. latest by the time the invention was made, by the time the application was filed, by the time one uses the claimed method, or else.

The phrase “the genome sequence” recited in line 3 of claim 2 lacks clear antecedent basis. There appear two types of genome sequences recited in claim 1, the earlier version of a genome sequence and the latest genome sequence. It is not clear what is referred to in claim 2 by “the genome sequence.” Ditto for the same phrase “the genome sequence” recited in lines 2-5 of claim 3.

The phrase “in amore number in an organism” recited in line 3 of claim 4 is confusing. It is not clear what is meant by “in a more number.”

Clarification of the metes and bounds of the claims is requested.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also

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Shubo (Joe) Zhou, Ph.D.

A handwritten signature in black ink, appearing to read "Shubo Zhou", followed by the date "9/24/02".

Patent Examiner